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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MICROSPHERIX LLC, Plaintiff, *v.* MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V. AND ORGANON USA, INC. Defendants.	Civil Action No. 2:17-cv-03984 (CCC)(JBC)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR A JURY TRIAL

Plaintiff Microspherix LLC ("Microspherix"), for its Complaint against Defendants Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V. and Organon USA, Inc. (collectively, "Merck" or "Defendants"), hereby alleges as follows:

PARTIES

1. Plaintiff Microspherix is a Florida corporation having a principal place of business at 21283 Rockledge Lane, Boca Raton, Florida 33428 in Palm Beach County.

2. Defendant Merck Sharp & Dohme Corp. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

3. Defendant Merck Sharp & Dohme B.V. is incorporated in the Netherlands with a place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands.

4. Defendant Organon USA, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, NJ, 07033 and One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

5. Defendant Merck Sharp & Dohme Corp. is and was, at all relevant times, engaged in the business of researching, developing, designing, manufacturing, distributing, supplying, selling, marketing and/or introducing in interstate commerce, either directly or indirectly through third parties or related entities, its products, including the etonogestrel implant, Nexplanon.

6. Nexplanon is manufactured for Defendant Merck Sharp & Dohme Corp.

7. Defendant Merck Sharp & Dohme Corp. conducts and transacts business operations throughout the United States, including in the State of New Jersey, and derives substantial revenue from interstate commerce.

8. United States Patent No. 8,722,037 (the "'037 Patent") is listed in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, and identified at www.merck/com/product/patent/home.html as the patent associated with Defendants' Nexplanon product.

9. The '037 Patent is assigned on the face of the patent to Defendant Merck Sharp & Dohme B.V.

10. Defendant Merck Sharp & Dohme B.V. is and was, at all relevant times, engaged in the business of researching, developing, designing, manufacturing, distributing, supplying, selling, marketing and/or introducing in interstate commerce, either directly or indirectly through third parties or related entities, its products, including the etonogestrel implant, Nexplanon.

11. Defendant Merck Sharp & Dohme B.V. conducts and transacts business operations throughout the United States, including in the State of New Jersey, and derives substantial revenue from interstate commerce.

12. Defendant Organon USA, Inc. is listed as the "Labeler Name" for Nexplanon in the National Drug Code Directory.

13. A true and correct copy of the National Drug Code Directory for Nexplanon is attached hereto as **Exhibit A**.

14. A true and correct copy of a letter from the FDA to Organon USA, Inc. regarding the labeling of Nexplanon is attached hereto as **Exhibit B**.

15. According to the FDA website, a labeler "may be either a manufacturer, including a repackager or relabeler, or, for drugs subject to private labeling arrangements, the entity under whose own label or trade name the product will be distributed." (https://www.fda.gov/drugs/informationondrugs/ucm142438.htm)

16. Defendant Organon USA, Inc. is and was, at all relevant times, engaged in the business of researching, developing, designing, manufacturing, distributing, supplying, selling, marketing and/or introducing in interstate commerce, either directly or indirectly through third parties or related entities, its products, including the etonogestrel implant, Nexplanon.

17. Defendant Organon USA, Inc. conducts and transacts business operations throughout the United States, including in the State of New Jersey, and derives substantial revenue from interstate commerce.

NATURE OF THE ACTION

18. This is a claim for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*. This action arises out of Defendants' current manufacture, use, sale and/or offer to sell within the United States, Defendants' implantable contraceptive as well as accompanying prescriber and patient information instructing use of this contraceptive.

19. Dr. Edward J. Kaplan is a practicing radiation oncologist and a named inventor on a number of patents directed to medical implant devices which release a therapeutic agent. A distinguishing feature of Dr. Kaplan's claimed inventions relates to a novel and innovative use of a radiopaque marker to help a physician implant the medical device in the correct location for delivery of a therapeutic agent.

20. Defendants' contraceptive is known as Nexplanon, an etonogestrel implant with a radiopaque marker. Nexplanon was preceded by another implantable contraceptive device known as Implanon, approved in 2001. Implanon lacked a radiopaque marker.

21. Implanon had a propensity to migrate after insertion into the body and become lost. Improper insertion or non-insertion also resulted in unwanted pregnancies. This resulted at least in part from a lack of a means to locate and confirm the correct location of the Implanon device after insertion.

22. Marketing for Implanon in the U.S. ceased by 2012, at which point Nexplanon was the only available single-rod implant in the U.S.

23. Nexplanon improved upon Implanon by including a radiopaque marker allowing for the correct insertion of the device. Nexplanon was also more easily removed than Implanon because it could be located using diagnostic imaging.

JURISDICTION

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

25. This Court has personal jurisdiction over Defendant Merck Sharp & Dohme Corp. because, among other reasons, Defendant Merck Sharp & Dohme Corp. is incorporated in the State of New Jersey and has a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

26. This Court has personal jurisdiction over Defendant Merck Sharp & Dohme Corp. because, among other reasons, Defendant Merck Sharp & Dohme Corp. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey and having a registered agent for service of process in New Jersey.

27. This Court has personal jurisdiction over Defendant Merck Sharp & Dohme Corp. because, among other reasons, Defendant Merck Sharp & Dohme Corp. has "engaged in substantial and not isolated activity within this state" by conducting and transacting business operations throughout the United States, including in the State of New Jersey, and deriving substantial revenue from interstate commerce.

28. This Court also has personal jurisdiction over Defendant Merck Sharp & Dohme Corp. because, among other reasons, Merck Sharp & Dohme Corp. has established minimum contacts within the forum such that the exercise of jurisdiction over Defendant Merck Sharp & Dohme Corp. will not offend traditional notions of fair play and substantial justice. For instance, Defendant Merck Sharp & Dohme Corp. has placed products that practice the claimed inventions of the Patents-in-Suit into the stream of commerce with the reasonable expectation and/or knowledge that purchasers and users of such products were located within the District of New Jersey. Defendant Merck Sharp & Dohme Corp. has sold, advertised, marketed and/or distributed products in this District that practice the claimed inventions of the Patents-in-Suit.

29. Additionally, this Court also has personal jurisdiction over Defendant Merck Sharp & Dohme Corp. because Merck Sharp & Dohme Corp. has previously elected to avail itself of the benefits of litigating its patent disputes in the District of New Jersey. *See, e.g., Merck Sharp & Dohme Corp. v. Actavis Lab. FL, Inc.*, Civil Action No. 2:15-CV-06541 (D.N.J.); *Merck Sharp & Dohme Corp. v. Impax Labs., Inc.*, Civil Action No. 2:10-CV-04270 (D.N.J.); *Merck Sharp & Dohme Corp. v. Accord Healthcare, Inc.*, Civil Action No. 3:12-CV-03324 (D.N.J.); *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, Civil Action No. 2:12-CV-06077 (D.N.J.).

30. This Court has personal jurisdiction over Defendant Merck Sharp & Dohme B.V. because, among other reasons, Defendant Merck Sharp & Dohme B.V. has "engaged in substantial and not isolated activity within this state" by conducting and transacting business operations throughout the United States, including in the State of New Jersey, and deriving substantial revenue from interstate commerce.

31. This Court also has personal jurisdiction over Defendant Merck Sharp & Dohme B.V. because, among other reasons, Merck Sharp & Dohme B.V. has established minimum contacts within the forum such that the exercise of jurisdiction over Defendant Merck Sharp & Dohme B.V. will not offend traditional notions of fair play and substantial justice. For instance, Defendant Merck Sharp & Dohme B.V. has placed products that practice the claimed inventions of the Patents-in-Suit into the stream of commerce with the reasonable expectation and/or knowledge that purchasers and users of such products were located within the District of New Jersey. Defendant Merck Sharp & Dohme B.V. has manufactured, sold, advertised, marketed and/or distributed products in this District that practice the claimed inventions of the Patents-in-Suit.

32. This Court has personal jurisdiction over Defendant Organon USA, Inc. because, among other reasons, Defendant Organon USA, Inc. is incorporated in the State of New Jersey and has a principal place of business at 2000 Galloping Hill Road, Kenilworth, NJ, 07033 and One Merck Drive, Whitehouse Station, New Jersey 08889-0100.

33. This Court has personal jurisdiction over Defendant Organon USA, Inc. because, among other reasons, Defendant Organon USA, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey and having a registered agent for service of process in New Jersey.

34. This Court has personal jurisdiction over Defendant Organon USA, Inc. because, among other reasons, Defendant Organon USA, Inc. has "engaged in substantial and not isolated activity within this state" by conducting and transacting business operations throughout the United States, including in the State of New Jersey, and deriving substantial revenue from interstate commerce.

35. This Court also has personal jurisdiction over Defendant Organon USA, Inc. because, among other reasons, Organon USA, Inc. has established minimum contacts within the forum such that the exercise of jurisdiction over Defendant Organon USA, Inc. will not offend traditional notions of fair play and substantial justice. For instance, Defendant Organon USA, Inc. has placed products that practice the claimed inventions of the Patents-in-Suit into the stream of commerce with the reasonable expectation and/or knowledge that purchasers and users of such products were located within the District of New Jersey. Defendant Organon USA, Inc. has sold, advertised, marketed and/or distributed products in this District that practice the claimed inventions of the Patents-in-Suit.

36. Additionally, this Court also has personal jurisdiction over Defendant Organon USA, Inc. because Organon USA, Inc. has previously elected to avail itself of the benefits of litigating its patent disputes in the District of New Jersey. *See, e.g.*, *Merck & Co., Inc. v. Sun Pharma. Indus., Ltd.*, Civil Action No. 3:12-CV-05374 (D.N.J.).

VENUE

37. Venue is proper as to each Defendant in this district pursuant to the provisions of 28 U.S.C. §§ 1391(b)(1), (2), (3) or (c)(3) and 1400.

38. Defendant Merck Sharp & Dohme Corp. is incorporated in the State of New Jersey, has a regular and established place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100, and has committed acts of infringement in the District of New Jersey.

Accordingly, venue is proper in this district as to Defendant Merck Sharp & Dohme Corp., pursuant to the provisions of 28 U.S.C. § 1400(b).

39. Defendant Organon USA, Inc. is incorporated in the State of New Jersey, has a regular and established place of business at 2000 Galloping Hill Road, Kenilworth, NJ, 07033, and One Merck Drive, Whitehouse Station, New Jersey 08889-0100, and has committed acts of infringement in the District of New Jersey. Accordingly, venue is proper in this district as to Defendant Organon USA, Inc., pursuant to the provisions of 28 U.S.C. § 1400(b).

40. Defendant Merck Sharp & Dohme B.V. does not reside in the United States. Accordingly, venue is proper in this district pursuant to the provisions of 28 U.S.C. §§ 1391(c)(3) and 1400(b).

THE PATENTS-IN-SUIT

The '402 Patent

41. United States Patent No. 9,636,402 (the "'402 Patent"), titled "Flexible and/or Elastic Brachytherapy Seed or Strand," was duly and legally issued by the United States Patent and Trademark Office on May 2, 2017.

42. A true and correct copy of the '402 Patent is attached hereto as **Exhibit C**.

43. Microspherix is the assignee of the '402 Patent and has the right to sue and recover damages for any current or past infringement of the '402 Patent. The '402 Patent is directed to, among other things, "[a] flexible or elastic brachytherapy strand that includes an imaging marker and/or a therapeutic, diagnostic or prophylactic agent such as a drug in a biocompatible carrier that can be delivered to a subject upon implantation into the subject through the bore of a brachytherapy implantation needle…." ('402 Patent Abstract.)

The '193 Patent

44. United States Patent No. 6,514,193 (the "'193 Patent"), titled "Method of Administering a Therapeutically Active Substance," was duly and legally issued by the United States Patent and Trademark Office on February 4, 2003.

45. A true and correct copy of the '193 Patent is attached hereto as **Exhibit D**.

46. Microspherix is the assignee of the '193 Patent and has the right to sue and recover damages for any current or past infringement of the '193 Patent.

47. The '193 Patent is directed to, among other things, "[a] method for administering a therapeutically active component including a non-radioactive drug to a target tissue in a subject…." ('193 Patent Abstract.)

The '401 Patent

48. United States Patent No. 9,636,401 (the "'401 Patent"), titled "Flexible and/or Elastic Brachytherapy Seed or Strand," was duly and legally issued by the United States Patent and Trademark Office on May 2, 2017.

49. A true and correct copy of the '401 Patent is attached hereto as **Exhibit E**.

50. Microspherix is the assignee of the '401 Patent and has the right to sue and recover damages for any current or past infringement of the '401 Patent.

51. The '401 Patent is directed to, among other things, "[a] flexible or elastic brachytherapy strand that includes an imaging marker and/or a therapeutic, diagnostic or prophylactic agent such as a drug in a biocompatible carrier that can be delivered to a subject upon implantation into the subject through the bore of a brachytherapy implantation needle…." ('401 Patent Abstract.)

The '835 Patent

52. United States Patent No. 8,821,835 (the "'835 Patent"), titled "Flexible and/or Elastic Brachytherapy Seed or Strand," was duly and legally issued by the United States Patent and Trademark Office on September 2, 2014.

53. A true and correct copy of the '835 Patent is attached hereto as **Exhibit F**.

54. Microspherix is the assignee of the '835 Patent and has the right to sue and recover damages for any current or past infringement of the '835 Patent.

55. The '835 Patent is directed to, among other things, "[a] flexible or elastic brachytherapy strand that includes an imaging marker and/or a therapeutic, diagnostic or prophylactic agent such as a drug in a biocompatible carrier that can be delivered to a subject upon implantation into the subject through the bore of a brachytherapy implantation needle…." ('835 Patent Abstract.)

DEFENDANTS' NEXPLANON PRODUCT

56. Merck developed Nexplanon (etonogestrel implant).

57. Nexplanon consists of an implantable progestin (etonogestrel) contraceptive having a radiopaque, non-radioactive marker, which is pre-loaded in the needle of a disposable applicator.

58. Merck has been advertising, marketing, distributing and/or selling Nexplanon in the United States as of, or subsequent to, 2011.

59. Nexplanon is a follow-on product that replaced a prior medical device known as Implanon.

60. Implanon was advertised, marketed, distributed and/or sold by Merck in the United States as of, or prior to, 2012.

61. Implanon was withdrawn from the United States market at least due in part because of incidences of unwanted pregnancies occurring from improper implantation of the device.

62. A difference between Implanon and Nexplanon is that Nexplanon includes a radiopaque marker.

63. The radiopaque marker allows medical imaging devices such as medical X-ray imaging to be used to assist with locating and situating the implant.

64. Accompanying the Nexplanon product is the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016).

65. A true and correct copy of the Nexplanon Prescribing Information accompanying the Nexplanon product is attached as **Exhibit G**.

66. A true and correct copy of the Nexplanon FDA-Approved Patient Labeling accompanying the Nexplanon product is attached as **Exhibit H**.

67. The Nexplanon Prescribing Information states that Nexplanon has an "Initial U.S. Approval" date of 2001.

COUNT I

Infringement of the '402 Patent

68. The foregoing paragraphs are incorporated by reference as if fully stated herein.

69. In violation of 35 U.S.C. § 271, Defendants are now, and have been directly (literally and/or under the doctrine of equivalents) and/or indirectly (by inducement or contributorily) infringing the '402 Patent.

70. Defendants have had knowledge of infringement of the '402 Patent at least as of the filing of the present complaint, including a letter dated June 5, 2017.

71. Defendants have infringed and continue to infringe one or more claims, including at least Claim 1, of the '402 Patent by making, using, selling, offering for sale, and/or importing Nexplanon.

72. Representative Claim 1 of the '402 Patent recites:

> A strand for administration of a therapeutic agent to a subject in need thereof comprising
>
> (a) a therapeutically effective amount of a therapeutic agent;
>
> (b) a biocompatible component comprising a polymer;
>
> (c) a radio-opaque material, wherein the radio-opaque material is encapsulated in the biocompatible component; and
>
> (d) a polymeric coating,
>
> wherein the therapeutic agent is a small molecule,
>
> wherein the polymeric coating covers the strand and
>
> wherein radiopaque material allows for the position of the strand to be determined following administration[;]
>
> wherein the strand is non-radioactive and does not contain a radioisotope.

('402 Patent at 24:9–19.)

73. Claim 1 of the '402 Patent recites in part, "[a] strand for administration of a therapeutic agent to a subject in need thereof…" ('402 Patent at 24:9–10.) Defendants' Nexplanon product satisfies this claim limitation.

74. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is a "rod shaped implant" which is "4 cm in length with a diameter of 2 mm…." (Nexplanon Prescribing Information at 1, 19.)

75. The '402 Patent describes a strand, for example, as "typically hav[ing] a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge)…." ('402 Patent at 5:47–50.)

76. The diameter of Nexplanon is 2 millimeters, which is less than 2.7 millimeters.

77. Thus, Defendants' Nexplanon product can pass through the bore of a needle having an interior diameter of less than 2.7 millimeters.

78. As such, Defendants' Nexplanon product may be considered, among other things, a strand.

79. Nexplanon contains "a progestin indicated for use by women to prevent pregnancy." (Nexplanon Prescribing Information at 1.)

80. Accordingly, Defendants' Nexplanon product (a strand) administers a therapeutic agent to a person in need thereof.

81. Claim 1 of the '402 Patent also recites in part, "(a) a therapeutically effective amount of a therapeutic agent…" ('402 Patent at 24:10–11.) Defendants' Nexplanon product satisfies this claim limitation.

82. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of "68 mg of the synthetic progestin etonogestrel," which has been found by the FDA to be safe and effective in preventing pregnancy. (Nexplanon Prescribing Information at 1, 19.)

83. Accordingly, Defendants' Nexplanon product comprises a therapeutically effective amount of a therapeutic agent.

84. Claim 1 of the '402 Patent also recites in part, "(b) a biocompatible component comprising a polymer…" ('402 Patent at 24:11–12.) Defendants' Nexplanon product satisfies this claim limitation.

85. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon

product is comprised of "an ethylene vinyl acetate (EVA) copolymer core." (Nexplanon Prescribing Information at 19.)

86. Nexplanon has been approved by the FDA, and Nexplanon is comprised of EVA (a polymer). (Nexplanon Prescribing Information at 1, 19.)

87. EVA has been approved for human use by the FDA.

88. EVA is biocompatible.

89. Accordingly, Defendants' Nexplanon product is comprised of a biocompatible component comprising a polymer.

90. Claim 1 of the '402 Patent also recites in part, "a radio-opaque material, wherein the radio-opaque material is encapsulated in the biocompatible component…" ('402 Patent at 24:12–14.) Defendants' Nexplanon product satisfies this claim limitation.

91. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of "an ethylene vinyl acetate (EVA) copolymer core, containing 68 mg of the synthetic progestin etonogestrel, barium sulfate (radiopaque ingredient), and may also contain magnesium stearate…." (Nexplanon Prescribing Information at 19.)

92. Accordingly, the radiopaque material (barium sulfate) is encapsulated in the biocompatible component (EVA copolymer core).

93. Claim 1 of the '402 Patent also recites in part, "(d) a polymeric coating…" ('402 Patent at 24:14.) Defendants' Nexplanon product satisfies this claim limitation.

94. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of an "EVA copolymer core, containing 68 mg of the synthetic progestin

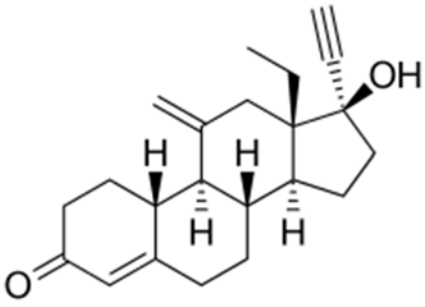
etonogestrel, barium sulfate (radiopaque ingredient), and may also contain magnesium stearate, surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

95. Accordingly, the "EVA copolymer skin" is a polymeric coating.

96. Claim 1 of the '402 Patent also recites in part, "wherein the therapeutic agent is a small molecule…" ('402 Patent at 24:15.) Defendants' Nexplanon product satisfies this claim limitation.

97. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of the active ingredient etonogestrel, also known as 13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17α-pregn-4-en-20-yn-3-one. (Nexplanon Prescribing Information at 19.)

98. Etonogestrel is a chemical compound having a molecular weight of about 324.46 g/mol and the following chemical structure:



(Nexplanon Prescribing Information at 19.)

99. Accordingly, Defendants' Nexplanon product is comprised of a small molecule therapeutic agent.

100. Claim 1 of the '402 Patent also recites in part, "wherein the polymeric coating covers the strand…" ('402 Patent at 24:15–16.) Defendants' Nexplanon product satisfies this claim limitation.

101. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of an "EVA copolymer core, containing 68 mg of the synthetic progestin etonogestrel, barium sulfate (radiopaque ingredient), and may also contain magnesium stearate, surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

102. Accordingly, the polymeric coating (EVA copolymer skin) surrounds (covers) the strand.

103. Claim 1 of the '402 Patent also recites in part, "wherein radiopaque material allows for the position of the strand to be determined following administration…" ('402 Patent at 24:16–18.) Defendants' Nexplanon product satisfies this claim limitation.

104. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of barium sulfate, a radiopaque material, which allows for the position of the strand to be determined following administration, for example, by medical X-ray imaging. (Nexplanon Prescribing Information at 7, 19.)

105. Claim 1 of the '402 Patent also recites in part, "wherein the strand is non-radioactive and does not contain a radioisotope…" ('402 Patent at 24:18–19.) Defendants' Nexplanon product satisfies this claim limitation.

106. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), do not indicate that Defendants' Nexplanon product is radioactive, or contains radioisotopes.

107. If Defendants' Nexplanon product contained radioactive materials, the Nexplanon Prescribing Information and/or Nexplanon FDA-Approved Patient Labeling would indicate this.

108. Accordingly, Defendants' Nexplanon product is non-radioactive and does not contain a radioisotope.

109. Defendants directly infringe (literally or under the doctrine of equivalents) and/or indirectly infringe (by inducement or contributorily) the claims of the '402 Patent before the expiration thereof, including but not limited to, representative Claim 1 as well as Claims 2–19.

110. Defendants' Nexplanon product is accompanied by the Nexplanon Prescribing Information, directed primarily to health-care providers, as well as the FDA-Approved Patient Labeling, directed primarily to patients. (*See, e.g.,* **Exhibits G and H**.)

111. The Nexplanon Prescribing Information expressly encourages and instructs healthcare providers to use Defendants' Nexplanon product in their patients.

112. The FDA-Approved Patient Labeling expressly encourages use of Defendants' Nexplanon product by patients under the direction of a healthcare provider.

113. Thus, a patient and/or healthcare provider, following the Nexplanon Prescribing Information and/or FDA-Approved Patient Labeling, will infringe the '402 Patent by using Defendants' Nexplanon product.

114. Defendants know or should reasonably know that distributing the Nexplanon Prescribing Information and FDA-Approved Patient Labeling with Nexplanon will induce healthcare providers and/or patients to use Defendants' Nexplanon product, or contribute to an infringing use of Defendants' Nexplanon product.

115. Defendants, as well as patients and healthcare providers following the Nexplanon Prescribing Information or FDA-Approved Patient Labeling, directly and/or indirectly infringe literally and/or under the doctrine of equivalents, the '402 Patent.

116. Neither Nexplanon nor the use of Nexplanon according to the Nexplanon Prescribing Information are a staple article or commodity of commerce suitable for substantial noninfringing use.

117. Microspherix has been and continues to be damaged by Defendants infringement of the ’402 Patent.

COUNT II

Infringement of the ’193 Patent

118. The foregoing paragraphs are incorporated by reference as if fully stated herein.

119. In violation of 35 U.S.C. § 271, Defendants are now, and have been directly (literally or under the doctrine of equivalents) and/or indirectly (by inducement or contributorily) infringing the ’193 Patent.

120. Defendants have had knowledge of infringement of the ’193 Patent at least as of the filing of the present complaint, including a letter dated June 5, 2017.

121. Defendants have infringed and continue to infringe one or more claims, including at least Claim 1, of the ’193 Patent.

122. Representative Claim 1 of the ’193 Patent recites:

> A method for administering a therapeutically active component to a target tissue in a subject, the method comprising the steps of:
>
> providing a brachytherapy seed comprising
>
> a non-metal biocompatible component,
>
> a therapeutically active component comprising a non-radioactive drug, and
>
> a radiopaque marker,
>
> said biocompatible component being (a) physically associated with a therapeutically active component and (b) in contact with said radiopaque marker,
>
> wherein said brachytherapy seed has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge);

> providing a brachytherapy implantation instrument comprising at least one brachytherapy implantation needle having a bore having an interior diameter of less than about 2.7 millimeters (10 gauge), and being adapted to accept the brachytherapy seed into the bore of the at least one brachytherapy implantation needle and deliver the accepted implantation device into a target tissue;
>
> introducing the brachytherapy seed into the bore of the at least one implantation needle of the brachytherapy implantation instrument;
>
> introducing at least a portion of the at least one brachytherapy implantation needle into a target tissue in the subject; and
>
> actuating the brachytherapy implantation instrument such that the brachytherapy seed is delivered through the bore of the brachytherapy implantation needle into the target tissue.

('193 Patent at 16: 36–67.)

123. Claim 1 of the '193 Patent recites in part, "[a] method for administering a therapeutically active component to a target tissue in a subject…" ('193 Patent at 16:36–38.)

124. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of "68 mg of the synthetic progestin etonogestrel," which has been found by the FDA to be safe and efficacious in preventing pregnancy. (Nexplanon Prescribing Information at 1, 19.)

125. Thus, Defendants' Nexplanon product is comprised of a therapeutically active component.

126. The Nexplanon FDA-Approved Patient Labeling (revised 03/2016) discloses a method for administering Nexplanon to a target tissue in a subject. (Nexplanon Prescribing Information at 4–7.)

127. Accordingly, Healthcare providers following Defendants' instructions for use in the Nexplanon Prescribing Information will administer a therapeutically active component to a target tissue in a subject.

128. Claim 1 of the '193 Patent also recites in part, "providing a brachytherapy seed…." ('193 Patent at 16:39.)

129. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is a "rod shaped implant" which is "4 cm in length with a diameter of 2 mm…." (Nexplanon Prescribing Information at 1, 19.)

130. In one embodiment, the '193 Patent describes "seeds shaped into a cylinder (or rod) having a diameter of between about 0.8 to 3 millimeters…and a length greater than the diameter…." ('193 Patent at 6:12–15, 28.)

131. In another embodiment, the '193 Patent describes a seed that "has a size and shape that can pass through a bore having a diameter of less than about 2.7 millimeters." ('193 Patent at 5:45–46.)

132. The diameter of Nexplanon (2 mm) is between 0.8 and 3 mm, and the length of Nexplanon (4 cm) is equivalent to 40 mm.

133. Accordingly, Nexplanon may be considered, among other things, a seed including a brachytherapy seed.

134. Claim 1 of the '193 Patent also recites in part, "a non-metal biocompatible component…" ('193 Patent at 16:39–40.)

135. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of "an ethylene vinyl acetate (EVA) copolymer core." (Nexplanon Prescribing Information at 19.)

136. EVA is not a metal.

137. Nexplanon has been approved by the FDA, and Nexplanon is comprised of EVA. (Nexplanon Prescribing Information at 1, 19.)

138. EVA has been approved for human use by the FDA.

139. EVA is biocompatible.

140. Accordingly, Defendants' Nexplanon product is comprised of a non-metal biocompatible component.

141. Claim 1 of the '193 Patent also recites in part, "a therapeutically active component comprising a non-radioactive drug…" ('193 Patent at 16:41–42.)

142. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of "68 mg of the synthetic progestin etonogestrel," which has been found by the FDA to be safe and efficacious in preventing pregnancy. (Nexplanon Prescribing Information at 1, 19.)

143. Thus, Defendants' Nexplanon product is comprised of a therapeutically active component.

144. The Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), do not indicate that Defendants' Nexplanon product is comprised of any radioactive component or drug.

145. If Defendants' Nexplanon product was comprised of radioactive materials, the Nexplanon Prescribing Information and/or Nexplanon FDA-Approved Patient Labeling would indicate this.

146. Accordingly, Defendants' Nexplanon product contains a therapeutically active component comprising a non-radioactive drug.

147. Claim 1 of the ’193 Patent also recites in part, “a radiopaque marker…” (’193 Patent at 16:41–42.).

148. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants’ Nexplanon product is comprised of barium sulfate, a radiopaque material that may be used as a marker. (Nexplanon Prescribing Information at 7, 19.)

149. Claim 1 of the ’193 Patent also recites in part, “said biocompatible component being (a) physically associated with a therapeutically active component and (b) in contact with said radiopaque marker…” (’193 Patent at 16:42–45.)

150. The ’037 Patent which discloses Defendants’ Nexplanon product recites the following:

> The core material was prepared by adding the desired amount (e.g. 52.5 wt % etonogestrel, 36 wt % EVA, 11.5 wt % Barium sulphate) of ingredients to a stainless steel drum after which the powder mixture was pre-mixed by rotating the drum on a rhönrad, or equivalent, at 47 rpm. The powder mixture was subsequently fed to a Berstorff ZE25 co-rotating twin screw extruder (or equivalent) and blend extruded at an extrusion temperature of 125° C. Blend extrusion resulted in strands in which etonogestrel (3-keto desogestrel) and barium sulphate were homogeneously dispersed in the EVA-28 matrix.

(’037 Patent at 5:14–26.)

151. Accordingly, Defendants’ Nexplanon product comprises an EVA biocompatible component which is physically associated with the etonogestrel (therapeutic active component) and in contact with the barium sulfate (radiopaque marker).

152. Claim 1 of the ’193 Patent also recites in part, “wherein said brachytherapy seed has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge)…” (’193 Patent at 16:45–48.)

153. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is a "rod-shaped implant" which is "4 cm in length with a diameter of 2 mm…." (Nexplanon Prescribing Information at 1, 19.)

154. The diameter of Nexplanon is 2 millimeters, which is less than 2.7 millimeters.

155. Accordingly, the brachytherapy seed (Nexplanon) has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than 2.7 millimeters.

156. Claim 1 of the '193 Patent also recites in part, "providing a brachytherapy implantation instrument comprising at least one brachytherapy implantation needle having a bore having an interior diameter of less than about 2.7 millimeters (10 gauge), and being adapted to accept the brachytherapy seed into the bore of the at least one brachytherapy implantation needle and deliver the accepted implantation device into a target tissue…" ('193 Patent at 16:49–56.)

157. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is supplied "pre-loaded in the needle of a disposable applicator." (Nexplanon Prescribing Information at 1.)

158. The disposable applicator is used as an instrument to implant Nexplanon. (Nexplanon Prescribing Information at 4–7.)

159. The Nexplanon implantation instrument is comprised of at least one implantation needle. (Nexplanon Prescribing Information at 1, 4–7.)

160. Defendants' Nexplanon product is described as a "rod-shaped implant" which is "4 cm in length with a diameter of 2 mm…." (Nexplanon Prescribing Information at 1, 19.)

161. The diameter of Nexplanon is 2 millimeters, which is less than 2.7 millimeters.

162. The needle of the implantation instrument (disposable applicator), has an interior diameter of less than 2.7 millimeters.

163. Since Defendants' Nexplanon product is supplied "pre-loaded in the needle of a disposable applicator," the bore of the implantation needle of the implantation instrument (disposable applicator) is able to accept the brachytherapy seed (Nexplanon). (Nexplanon Prescribing Information at 1.)

164. Nexplanon is implanted into subjects, e.g., for use as a contraceptive. (Nexplanon Prescribing Information at 1.)

165. The implantation instrument (disposable applicator) delivers the implantable Nexplanon product into a target tissue. (Nexplanon Prescribing Information at 3–7.)

166. Accordingly, Nexplanon is supplied with an implantation instrument which has at least one implantation needle.

167. Accordingly, the bore of the implantation needle has an interior diameter of less than 2.7 millimeters.

168. Accordingly, the implantation needle is adapted to accept the brachytherapy seed (Nexplanon) into the bore of the implantation needle.

169. Accordingly, the implantation instrument (disposable applicator) is able to deliver the implantable Nexplanon product into a target tissue.

170. Claim 1 of the '193 Patent also recites in part, "introducing the brachytherapy seed into the bore of the at least one implantation needle of the brachytherapy implantation instrument…" ('193 Patent at 16:57–59.)

171. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon

product is supplied "pre-loaded in the needle of a disposable applicator." (Nexplanon Prescribing Information at 1.)

172. The disposable applicator is used as an instrument to implant Nexplanon. (Nexplanon Prescribing Information at 4–7.)

173. The Nexplanon implantation instrument (disposable applicator) is comprised of at least one implantation needle. (Nexplanon Prescribing Information at 1, 4–7.)

174. Accordingly, the brachytherapy seed (Nexplanon) has been introduced into the bore of the implantation needle of the implantation instrument (disposable applicator).

175. Claim 1 of the '193 Patent also recites in part, "introducing at least a portion of the at least one brachytherapy implantation needle into a target tissue in the subject…" ('193 Patent at 16:60–62.)

176. The Nexplanon Prescribing Information (revised 12/2016) recites the following:

> Step 2. Identify the insertion site, which is at the inner side of the non-dominant upper arm about 8-10 cm (3-4 inches) above the medial epicondyle of the humerus, avoiding the sulcus (groove) between the biceps and triceps muscles and the large blood vessels and nerves that lie there in the neurovascular bundle deeper in the subcutaneous tissue (Figure 2). The implant should be inserted subdermally just under the skin…. Step 3. Make two marks with a sterile marker: first, mark the spot where the etonogestrel implant will be inserted, and second, mark a spot a few centimeters proximal to the first mark (Figure 2). This second mark will later serve as a direction guide during insertion.

(Nexplanon Prescribing Information at 4.)

177. The Nexplanon Prescribing Information (revised 12/2016) recites the following: "Step 9. Puncture the skin with the tip of the needle slightly angled less than 30° (Figure 5)." (Nexplanon Prescribing Information at 5).

178. Accordingly, at least a portion of the needle of the disposable applicator used to implant Nexplanon is inserted into a target tissue in the patient. (Nexplanon Prescribing Information at 1, 4–7.)

179. Claim 1 of the '193 Patent also recites in part, "actuating the brachytherapy implantation instrument such that the brachytherapy seed is delivered through the bore of the brachytherapy implantation needle into the target tissue…" ('193 Patent at 16:63–67.)

180. The Nexplanon Prescribing Information (revised 12/2016) recites the following:

> Step 10. Lower the applicator to a horizontal position. While lifting the skin with the tip of the needle (Figure 6), slide the needle to its full length….Step 11. Keep the applicator in the same position with the needle inserted to its full length. If needed, you may use your free hand to keep the applicator in the same position during the following procedure. Unlock the purple slider by pushing it slightly down. Move the slider fully back until it stops (Figure 7). The implant is now in its final subdermal position, and the needle is locked inside the body of the applicator. The applicator can now be removed.

(Nexplanon Prescribing Information at 5–6.)

181. Accordingly, the implantation instrument (disposable applicator) is actuated such that Nexplanon is delivered through the bore of the implantation needle into the target tissue of the patient. (Nexplanon Prescribing Information at 1, 4–7.)

182. Use of Defendants' Nexplanon product according to its accompanying instructions directly infringes (literally or under the doctrine of equivalents) the claims of the '193 Patent before the expiration thereof, including but not limited to, representative Claim 1.

183. Defendants' Nexplanon product is accompanied by the Nexplanon Prescribing Information. (*See, e.g.*, **Exhibit G**.)

184. The Nexplanon Prescribing Information instructs healthcare providers as to the method of inserting Nexplanon in patients and thereby instructs a "method for administering a therapeutically active component to a target tissue in a subject."

185. Thus, a healthcare provider following Defendants' instructions for use in the Nexplanon Prescribing Information will infringe the '193 Patent.

186. Defendants, by providing instructions to use Nexplanon in an infringing manner, indirectly infringe (by inducement or contributorily) the claims of the ’193 Patent before the expiration thereof, including but not limited to, representative Claim 1.

187. Defendants know or should reasonably know that distributing the Nexplanon Prescribing Information with Nexplanon will induce healthcare providers to administer or implant Nexplanon according to the method found in the Nexplanon Prescribing Information.

188. Defendants, as well as healthcare providers following the Nexplanon Prescribing Information, directly and/or indirectly infringe literally and/or under the doctrine of equivalents, the ’193 Patent.

189. Neither Nexplanon nor the use of Nexplanon according to the Nexplanon Prescribing Information are a staple article or commodity of commerce suitable for substantial noninfringing use.

190. Microspherix has been and continues to be damaged by Defendants infringement of the ’193 Patent.

COUNT III

Infringement of the ’401 Patent

191. The foregoing paragraphs are incorporated by reference as if fully stated herein.

192. In violation of 35 U.S.C. § 271, Defendants are now, and have been directly (literally or under the doctrine of equivalents) and/or indirectly (by inducement or contributorily) infringing the ’401 Patent.

193. Defendants have had knowledge of infringement of the ’401 Patent at least as of the filing of the present complaint, including a letter dated June 5, 2017.

194. Defendants have infringed and continue to infringe one or more claims, including at least Claim 1, of the ’401 Patent by making, using, selling, offering for sale, and/or importing Nexplanon.

195. Representative Claim 1 of the ’401 Patent recites:

> A flexible non-radioactive strand for implantation into a subject, comprising:
>
> a marker component configured to allow for the determination of the position of the strand within a target tissue,
>
> the marker component having a length extending along a centerline of the marker component between a first end and a second end and having a substantially continuous wall bounding a hollow interior;
>
> a biocompatible component; and
>
> a therapeutic, prophylactic, and/or diagnostic agent,
>
> wherein the marker, biocompatible component and agent are disposed within the hollow interior;
>
> wherein the length of the marker component is greater than the diameter of the hollow interior, and
>
> wherein the substantially continuous wall includes at least one opening adapted to allow the agent to pass out of the hollow interior[;]
>
> wherein the strand do not contain a radioisotope.

(’401 Patent at 24:2–20.)

196. Claim 1 of the ’401 Patent recites in part, “[a] flexible non-radioactive strand for implantation into a subject…” (’401 Patent at 24:2–3.) Defendants’ Nexplanon product satisfies this claim limitation.

197. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants’ Nexplanon product is a “soft, flexible” “rod shaped implant” which is “4 cm in length with a diameter of 2 mm….” (Nexplanon Prescribing Information at 1, 19.)

198. The ’401 Patent describes a strand, for example, as “typically hav[ing] a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge)…” (’401 Patent at 5:42–45.)

199. The diameter of Nexplanon is 2 millimeters, which is less than 2.7 millimeters.

200. Thus, Defendants’ Nexplanon product can pass through the bore of a needle having an interior diameter of less than 2.7 millimeters.

201. As such, Defendants’ Nexplanon product may be considered, among other things, a strand.

202. The Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), do not indicate that Defendants’ Nexplanon product is radioactive.

203. If Defendants’ Nexplanon product contained radioactive materials, the Nexplanon Prescribing Information and/or Nexplanon FDA-Approved Patient Labeling would indicate this.

204. Nexplanon is implanted into subjects, e.g., for use as a contraceptive. (Nexplanon Prescribing Information at 1.)

205. Accordingly, Defendants’ Nexplanon product is a flexible, non-radioactive strand which is implanted into a subject.

206. Claim 1 of the ’401 Patent also recites in part, “a marker component configured to allow for the determination of the position of the strand within a target tissue…” (’401 Patent at 24:4–6.) Defendants’ Nexplanon product satisfies this claim limitation.

207. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), the Nexplanon implant is comprised of “an ethylene vinyl acetate (EVA) copolymer core, containing 68 mg of the

synthetic progestin etonogestrel, barium sulfate (radiopaque ingredient), and may also contain magnesium stearate, surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

208. Thus, the marker component is comprised of the EVA copolymer core, which contains barium sulfate (a radiopaque ingredient), and the EVA copolymer skin, which surrounds the EVA copolymer core.

209. The Nexplanon Prescribing Information recites the following: "[i]nsert one NEXPLANON subdermally just under the skin at the inner side of the non-dominant upper arm." (Nexplanon Prescribing Information at 1); "[a]lways verify the presence of the implant in the woman's arm immediately after insertion by palpation." (Nexplanon Prescribing Information at 6); "[i]f the rod is not palpable … [u]se other methods to confirm the presence of the implant. Given the radiopaque nature of the implant, suitable methods for localization are two-dimensional X-ray and X-ray computerized tomography (CT scan)" (Nexplanon Prescribing Information at 7).

210. Accordingly, the marker component is configured to allow for the determination of the position of the Nexplanon product (the strand) within a target tissue.

211. Claim 1 of the '401 Patent also recites in part, "the marker component having a length extending along a centerline of the marker component between a first end and a second end and having a substantially continuous wall bounding a hollow interior…" ('401 Patent at 24:6–10.) Defendants' Nexplanon product satisfies this claim limitation.

212. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is "rod shaped" (Nexplanon Prescribing Information at 1.)

213. Defendants' Nexplanon product is comprised of an EVA copolymer core, "surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

214. The EVA copolymer skin and the EVA copolymer core (marker component) is rod-shaped. (Nexplanon Prescribing Information at 1, 19.)

215. The rod-shaped marker component has a length extending along a centerline of the marker component. (Nexplanon Prescribing Information at 1, 19.)

216. The rod-shaped marker component has a first end and a second end. (Nexplanon Prescribing Information at 1, 19.)

217. The '037 Patent, which discloses Defendants' Nexplanon product, describes the "[p]reparation of a two layered implant … consisting of the core and a skin layer of EVA-14 copolymer." ('037 Patent at 5:8–14.)

218. The EVA copolymer skin surrounding the EVA copolymer core forms or is part of a substantially continuous wall.

219. Since the EVA copolymer skin surrounds the EVA copolymer core, the EVA copolymer skin would have an interior (hollow) space.

220. Thus, the marker component, which is comprised of the EVA copolymer skin and EVA copolymer core, has a length extending along a centerline of the marker component between a first end and a second end, and the EVA copolymer skin of the marker component has or forms part of a substantially continuous wall bounding an interior (hollow) space.

221. Claim 1 of the '401 Patent also recites in part, "a biocompatible component…" ('401 Patent at 24:10.) Defendants' Nexplanon product satisfies this claim limitation.

222. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon

product is comprised of "an ethylene vinyl acetate (EVA) copolymer core." (Nexplanon Prescribing Information at 19.)

223. Nexplanon has been approved by the FDA, and Nexplanon is comprised of EVA. (Nexplanon Prescribing Information at 1, 19.)

224. EVA has been approved for human use by the FDA.

225. EVA is biocompatible.

226. Accordingly, Defendants' Nexplanon product is comprised of a biocompatible component.

227. Claim 1 of the '401 Patent also recites in part, "a therapeutic, prophylactic, and/or diagnostic agent…" ('401 Patent at 24:11.) Defendants' Nexplanon product satisfies this claim limitation.

228. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of "68 mg of the synthetic progestin etonogestrel," which has been found by the FDA to be safe and effective in preventing pregnancy. (Nexplanon Prescribing Information at 1, 19.)

229. Accordingly, Defendants' Nexplanon product is comprised of a therapeutic and/or prophylactic agent.

230. Claim 1 of the '401 Patent also recites in part, "wherein the marker, biocompatible component and agent are disposed within the hollow interior…" ('401 Patent at 24:12-14.) Defendants' Nexplanon product satisfies this claim limitation.

231. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon

product is comprised of an "EVA copolymer core, containing 68 mg of the synthetic progestin etonogestrel, barium sulfate (radiopaque ingredient), and may also contain magnesium stearate, surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

232. The EVA copolymer core contains a biocompatible component (EVA), a radiopaque marker (barium sulfate), and a therapeutic agent (etonogestrel). (Nexplanon Prescribing Information at 19.)

233. Accordingly, the marker (barium sulfate), biocompatible component (EVA copolymer core) and agent (etonogestrel) are disposed within the interior (hollow) space, bounded at least in part by the EVA copolymer skin of the marker component.

234. Claim 1 of the '401 Patent also recites in part, "wherein the length of the marker component is greater than the diameter of the hollow interior…" ('401 Patent at 24:14–16.) Defendants' Nexplanon product satisfies this claim limitation.

235. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is a "rod shaped implant" which is "4 cm in length with a diameter of 2 mm…." (Nexplanon Prescribing Information at 1, 19.)

236. Accordingly, the length of Defendants' Nexplanon product (4 cm) is greater than the diameter of its interior (no more than 2 mm).

237. Defendants' Nexplanon product is comprised of an EVA copolymer core, "surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

238. The marker component of Nexplanon has an aspect ratio that is the same or substantially the same as the Nexplanon product.

239. For example, Example 1 of the ’037 Patent, describes the “preparation of a two layered implant … consisting of the core and a skin layer of EVA-14 copolymer.” (’037 Patent at 5:8–14.)

240. Example 1 of the ’037 Patent further recites, “[e]xtrusion lead to a co-axial fiber with a diameter of 2 mm and a skin thickness of 60 µm.” (’037 Patent at 5:34–35.)

241. Thus, the interior (hollow) space, bounded by the EVA copolymer skin of the marker component, has a diameter of no more than 2 mm.

242. Moreover, the ’037 Patent recites, “[t]he coaxial fiber was cut into 4.0 cm rods using a semiautomatic cutter (Diosynth or equivalent).” (’037 Patent at 5:37–38.)

243. Thus, the length of the marker component, which is comprised of the EVA copolymer skin and the EVA copolymer core, is 4 cm (40 mm).

244. Thus, accounting for the thickness of the EVA copolymer skin, the length of the marker component (40 mm) is greater than the diameter of the interior (hollow) space (no more than 2 mm).

245. Claim 1 of the ’401 Patent also recites in part, “wherein the substantially continuous wall includes at least one opening adapted to allow the agent to pass out of the hollow interior…” (’401 Patent at 24:17–19.) Defendants’ Nexplanon product satisfies this claim limitation.

246. The ’037 Patent, which discloses Defendants’ Nexplanon product recites, “[i]t can therefore be concluded that no or hardly any barium sulphate crystals migrated out of the implant through the open ends.” (’037 Patent at 9:4–6.)

247. The Nexplanon Prescribing Information recites, "[a]fter subdermal insertion of the etonogestrel implant, etonogestrel is released into the circulation and is approximately 100% bioavailable." (Nexplanon Prescribing Information at 19.)

248. Accordingly, Defendants' Nexplanon product includes at least one opening in its substantially continuous wall which allows the therapeutic agent to migrate out of the implant.

249. Claim 1 of the '401 Patent also recites in part, "wherein the strand do[es] not contain a radioisotope…" ('401 Patent at 24:19–20.) Defendants' Nexplanon product satisfies this claim limitation.

250. The Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), do not indicate that Defendants' Nexplanon product contains radioisotopes.

251. If Defendants' Nexplanon product contained radioisotopes, the Nexplanon Prescribing Information and/or Nexplanon FDA-Approved Patient Labeling would indicate this.

252. Accordingly, Defendants' Nexplanon product does not contain a radioisotope.

253. Defendants directly infringe (literally or under the doctrine of equivalents) and/or indirectly infringe (by inducement or contributorily) the claims of the '401 Patent before the expiration thereof, including but not limited to, representative Claim 1 and Claims 2–5, 13–16, 18–20, 23–25.

254. Defendants' Nexplanon product is accompanied by the Nexplanon Prescribing Information, directed primarily to health-care providers, as well as the FDA-Approved Patient Labeling, directed primarily to patients. (*See, e.g.*, **Exhibits G and H**.)

255. The Nexplanon Prescribing Information expressly encourages and instructs healthcare providers to use Defendants' Nexplanon product in their patients.

256. The FDA-Approved Patient Labeling expressly encourages use of Defendants' Nexplanon product by patients under the direction of a healthcare provider.

257. Thus, a patient and/or healthcare provider, following the Nexplanon Prescribing Information and/or FDA-Approved Patient Labeling, will infringe the '401 Patent by using Defendants' Nexplanon product.

258. Defendants know or should reasonably know that distributing the Nexplanon Prescribing Information and FDA-Approved Patient Labeling with Nexplanon will induce healthcare providers and/or patients to use Defendants' Nexplanon product, or contribute to an infringing use of Defendants' Nexplanon product.

259. Defendants, as well as patients and healthcare providers following the Nexplanon Prescribing Information or FDA-Approved Patient Labeling, directly and/or indirectly infringe literally and/or under the doctrine of equivalents, the '401 Patent.

260. Neither Nexplanon nor the use of Nexplanon according to the Nexplanon Prescribing Information are a staple article or commodity of commerce suitable for substantial noninfringing use.

261. Microspherix has been and continues to be damaged by Defendants infringement of the '401 Patent.

COUNT IV

Infringement of the '835 Patent

262. The foregoing paragraphs are incorporated by reference as if fully stated herein.

263. In violation of 35 U.S.C. § 271, Defendants are now, and have been directly (literally or under the doctrine of equivalents) and/or indirectly (by inducement or contributorily) infringing the '835 Patent.

264. Defendants have had knowledge of infringement of the ’835 Patent at least as of the filing of the present complaint, including a letter dated June 5, 2017.

265. Defendants have infringed and continue to infringe one or more claims, including at least Claim 1, of the ’835 Patent.

266. Representative Claim 1 of the ’835 Patent recites:

> A seed, for implantation into a subject, comprising:
>
> a marker component configured to allow for the determination of the position of the seed within a target tissue,
>
> the marker component having a length extending along a centerline of the marker component between a first end and a second end and having a substantially continuous wall bounding a hollow interior; and
>
> a therapeutic, prophylactic, and/or diagnostic agent,
>
> wherein the agent is disposed within the hollow interior;
>
> wherein the length of the marker component is greater than the diameter of the hollow interior and
>
> wherein the substantially continuous wall includes at least one opening adapted to allow the agent to pass out of the hollow interior.

(’835 Patent at 23:26–37.)

267. Claim 1 of the ’835 Patent recites in part, “[a] seed, for implantation into a subject…” (’835 Patent at 23:26.) Defendants’ Nexplanon product satisfies this claim limitation.

268. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants’ Nexplanon product is a “rod shaped implant” which is “4 cm in length with a diameter of 2 mm….” (Nexplanon Prescribing Information at 1, 19).

269. In one embodiment, the ’835 Patent describes “seeds shaped into a cylinder (or rod) having a diameter of between about 0.8 to 3 millimeters and a length of up to 40 millimeters [4cm].…” (’835 Patent at 14:31–35).

270. The diameter of Nexplanon (2 mm) is between 0.8 and 3 mm, and the length of Nexplanon (4 cm) is equivalent to 40 mm.

271. Nexplanon is implanted into subjects, e.g., for use as a contraceptive. (Nexplanon Prescribing Information at 1.)

272. Accordingly, Nexplanon may be considered, among other things, a seed for implantation in a subject.

273. Claim 1 of the '835 Patent recites in part, "a marker component configured to allow for the determination of the position of the seed within a target tissue…" ('835 Patent at 23:26–28.) Defendants' Nexplanon product satisfies this claim limitation.

274. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), the Nexplanon implant is comprised of "an ethylene vinyl acetate (EVA) copolymer core, containing 68 mg of the synthetic progestin etonogestrel, barium sulfate (radiopaque ingredient), and may also contain magnesium stearate, surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

275. Thus, the marker component is comprised of the EVA copolymer core, which contains barium sulfate (a radiopaque ingredient), and the EVA copolymer skin, which surrounds the EVA copolymer core.

276. The Nexplanon Prescribing Information recites the following: "[i]nsert one NEXPLANON subdermally just under the skin at the inner side of the non-dominant upper arm." (Nexplanon Prescribing Information at 1); "[a]lways verify the presence of the implant in the woman's arm immediately after insertion by palpation." (Nexplanon Prescribing Information at 6); "[i]f the rod is not palpable…[u]se other methods to confirm the presence of the implant.

Given the radiopaque nature of the implant, suitable methods for localization are two-dimensional X-ray and X-ray computerized tomography (CT scan)" (Nexplanon Prescribing Information at 7).

277. Accordingly, the marker component is configured to allow for the determination of the position of the Nexplanon product (the seed) within a target tissue.

278. Claim 1 of the '835 Patent recites in part, "the marker component having a length extending along a centerline of the marker component between a first end and a second end and having a substantially continuous wall bounding a hollow interior…" ('835 Patent at 23:28–32.) Defendants' Nexplanon product satisfies this claim limitation.

279. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is "rod shaped" (Nexplanon Prescribing Information at 1.)

280. Defendants' Nexplanon product is comprised of an EVA copolymer core, "surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

281. The EVA copolymer skin and the EVA copolymer core (marker component) is rod-shaped. (Nexplanon Prescribing Information at 1, 19.)

282. The rod-shaped marker component has a length extending along a centerline of the marker component. (Nexplanon Prescribing Information at 1, 19.)

283. The rod-shaped marker component has a first end and a second end. (Nexplanon Prescribing Information at 1, 19.)

284. The '037 Patent, which discloses Defendants' Nexplanon product, describes the "[p]reparation of a two layered implant … consisting of the core and a skin layer of EVA-14 copolymer." ('037 Patent at 5:8–14.)

285. The EVA copolymer skin surrounding the EVA copolymer core forms or is part of a substantially continuous wall.

286. Since the EVA copolymer skin surrounds the EVA copolymer core, the EVA copolymer skin would bound an interior (hollow) space.

287. Thus, the marker component has a length extending along a centerline of the marker component between a first end and a second end, and the EVA copolymer skin of the marker component has or forms part of a substantially continuous wall bounding an interior (hollow) space.

288. Claim 1 of the '835 Patent recites in part, "a therapeutic, prophylactic, and/or diagnostic agent…" ('835 Patent at 23:32–34.) Defendants' Nexplanon product satisfies this claim limitation.

289. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is comprised of "68 mg of the synthetic progestin etonogestrel," which has been found by the FDA to be safe and efficacious in preventing pregnancy. (Nexplanon Prescribing Information at 1, 19.)

290. Thus, Defendants' Nexplanon product is comprised of a therapeutic and/or prophylactic agent (etonogestrel).

291. Claim 1 of the '835 Patent recites in part, "wherein the agent is disposed within the hollow interior…" ('835 Patent at 23:32–34.) Defendants' Nexplanon product satisfies this claim limitation.

292. Defendants' Nexplanon product is comprised of an "EVA copolymer core, containing 68 mg of the synthetic progestin etonogestrel, barium sulfate (radiopaque ingredient),

and may also contain magnesium stearate, surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

293. The EVA copolymer core contains a biocompatible component (EVA), a radiopaque marker (barium sulfate), and a therapeutic agent (etonogestrel). (Nexplanon Prescribing Information at 19.)

294. Accordingly, the agent (etonogestrel) is disposed within the interior (hollow) space, bounded at least in part by the EVA copolymer skin of the marker component.

295. Claim 1 of the '835 Patent recites in part, "wherein the length of the marker component is greater than the diameter of the hollow interior…" ('835 Patent at 23:34–35.) Defendants' Nexplanon product satisfies this claim limitation.

296. As shown by at least the Nexplanon Prescribing Information (revised 12/2016) and the Nexplanon FDA-Approved Patient Labeling (revised 03/2016), Defendants' Nexplanon product is a "rod shaped implant" which is "4 cm in length with a diameter of 2 mm…." (Nexplanon Prescribing Information at 1, 19.)

297. Accordingly, the length of Defendants' Nexplanon product (4 cm) is greater than the diameter of its interior (no more than 2 mm).

298. Defendants' Nexplanon product is comprised of an EVA copolymer core, "surrounded by an EVA copolymer skin." (Nexplanon Prescribing Information at 19.)

299. The marker component of Nexplanon has the same aspect ratio as the Nexplanon product.

300. For example, Example 1 of the '037 Patent, describes the "[p]reparation of a two layered implant … consisting of the core and a skin layer of EVA-14 copolymer." ('037 Patent at 5:8–14.)

301. Example 1 of the ’037 Patent further recites, “[e]xtrusion lead to a co-axial fiber with a diameter of 2 mm and a skin thickness of 60 µm.” (’037 Patent at 5:34–35.)

302. Thus, the interior (hollow) space, bounded at least in part by the EVA copolymer skin of the marker component, has a diameter of no more than 2 mm.

303. Moreover, the ’037 Patent recites, “[t]he coaxial fiber was cut into 4.0 cm rods using a semiautomatic cutter (Diosynth or equivalent).” (’037 Patent at 5:37–38.)

304. Thus, the length of the marker component, which is comprised of the EVA copolymer skin and the EVA copolymer core, is 4 cm, which is equivalent to 40 mm.

305. Thus, accounting for the thickness of the EVA copolymer skin, the length of the marker component (40 mm) is greater than the diameter of the interior (hollow) space (no more than 2 mm).

306. Claim 1 of the ’835 Patent recites in part, “wherein the substantially continuous wall includes at least one opening adapted to allow the agent to pass out of the hollow interior…” (’835 Patent at 23:35–37.) Defendants’ Nexplanon product satisfies this claim limitation.

307. The ’037 Patent, which discloses Defendants’ Nexplanon product recites, “[i]t can therefore be concluded that no or hardly any barium sulphate crystals migrated out of the implant through the open ends.” (’037 Patent at 9:4–6.)

308. The Nexplanon Prescribing Information recites, “[a]fter subdermal insertion of the etonogestrel implant, etonogestrel is released into the circulation and is approximately 100% bioavailable.” (Nexplanon Prescribing Information at 19.)

309. Accordingly, Defendants’ Nexplanon product includes at least one opening in its substantially continuous wall which allows the therapeutic agent to migrate out of the implant.

310. Defendants directly infringe (literally or under the doctrine of equivalents) and/or indirectly infringe (by inducement or contributorily) the claims of the ’835 Patent before the expiration thereof, including but not limited to, representative Claim 1 and Claims 3–4, 14, 16–17.

311. Defendants’ Nexplanon product is accompanied by the Nexplanon Prescribing Information, directed primarily to health-care providers, as well as the FDA-Approved Patient Labeling, directed primarily to patients. (*See, e.g.*, **Exhibits G and H**.)

312. The Nexplanon Prescribing Information expressly encourages and instructs healthcare providers to use Defendants’ Nexplanon product in their patients.

313. The FDA-Approved Patient Labeling expressly encourages use of Defendants’ Nexplanon product by patients under the direction of a healthcare provider.

314. Thus, a patient and/or healthcare provider, following the Nexplanon Prescribing Information and/or FDA-Approved Patient Labeling, will infringe the ’835 Patent by using Defendants’ Nexplanon product.

315. Defendants know or should reasonably know that distributing the Nexplanon Prescribing Information and FDA-Approved Patient Labeling with Nexplanon will induce healthcare providers and/or patients to use Defendants’ Nexplanon product, or contribute to an infringing use of Defendants’ Nexplanon product.

316. Defendants, as well as patients and healthcare providers following the Nexplanon Prescribing Information or FDA-Approved Patient Labeling, directly and/or indirectly infringe literally and/or under the doctrine of equivalents, the ’835 Patent.

317. Neither Nexplanon nor the use of Nexplanon according to the Nexplanon Prescribing Information are a staple article or commodity of commerce suitable for substantial noninfringing use.

318. Microspherix has been and continues to be damaged by Defendants infringement of the ’835 Patent.

PRAYER FOR RELIEF

WHEREFORE, Microspherix respectfully requests that this Court enter judgment in its favor against Defendants, and grant the following relief:

A. Judgment that Defendants directly and/or indirectly infringe literally and/or under the doctrine of equivalents, at least one claim of the ’402, ’193, ’401 and ’835 Patents;

B. Judgment that the ’402, ’193, ’401 and ’835 Patents have not been proven invalid or unenforceable;

C. A preliminary and/or permanent injunction that enjoins Defendants, their officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from infringing the ’402, ’193, ’401 and/or ’835 Patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacture of which infringes the ’402, ’193, ’401 and/or ’835 Patents;

D. An award to Microspherix of damages adequate to compensate it for Defendants’ past infringement and any continuing or future infringement including interest, costs, and disbursements as justified under 35 U.S.C. § 284;

E. A declaration that this an exceptional case and an award to Microspherix of its reasonable attorneys’ fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

F. Such other and further relief in law or equity as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Microspherix hereby demands a trial by jury on all issues so triable.

* * *

Dated: October 10, 2017

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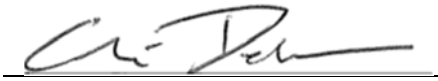
CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 10, 2017

KIRKLAND & ELLIS LLP



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